

**REMARKS**

Claims 1-15 are currently pending in the present application.

Claims 6-9 and 11 have been amended. Claims 6 and 7 have been amended to particularly point out and distinctly claim embodiments of Applicants' invention wherein the R<sup>5</sup> substituent represents trichloromethylsulfonyl. Claims 8 and 9 have been amended to specify that the reagent capable of adding hypobromous acid to the double bond at position 2, 3 of the compound of formula (III) comprises a component selected from two specific compounds. Claim 11 has been amended to be more clearly directed to those embodiments of Applicants' claimed invention wherein the acid comprises perchloric acid in an aqueous solution. Support for the amendments made herein can be found throughout the Specification, for example, at page 8, lines 9-10 and lines 13-14, and in the Examples. No new matter has been introduced by the amendments made herein. Additionally, no additional claims fees are necessitated by the amendments made herein. A complete listing of all claims ever presented is contained herein in accordance with 37 C.F.R. §1.121(c)(1). Thus, entry of the amendments made herein is proper and respectfully requested.

In the Office Action, the Examiner rejects claims 1-15 under 35 U.S.C. §102(b), as being anticipated by U.S. Patent No. 5,021,575 of King, *et al.* ("King"). Specifically, the Examiner contends that King discloses a method for introducing a 1,2-double bond into azasteroids. With respect to claims 6 and 7, the Examiner contends that compound (VII) disclosed in King at column 3, anticipates the claims when R<sup>5</sup> represents bromine in the claimed compounds. With respect to the claimed process, the Examiner contends that the process for introducing a double bond into the compounds of formula (I), as disclosed in King, through the formation of intermediate compounds, as set forth in columns 3-6, anticipates the claimed process when R<sup>5</sup> represents bromine. Applicants respectfully, but strenuously, traverse the Examiner's rejection and the arguments and contentions set forth in support thereof for the following reasons.

Contrary to the Examiner's assertions set forth in the Office Action, King fails to disclose each and every element of Applicants' claimed processes and compounds. It is well-settled that in order for a rejection under 35 U.S.C. §102 to be proper, each and every element of the claimed invention MUST be described, either expressly or inherently, in a single prior art

reference (*See*, MPEP § 2131, 8<sup>th</sup> Ed., Rev. 2, May, 2004). The disclosure of King does not meet this burden.

King is directed to methods for introducing 1,2-double bond into azasteroids. King describes processes for accomplishing the insertion of a double bond into azasteroids which comprises four steps. The first step is disclosed as involving the reaction of a compound of formula (I), as disclosed in King, with oxalyl chloride to produce a compound of formula (II). King discloses a second step which involves reacting the compound of formula (II) with bromine to produce a compound of formula (III). The third step disclosed in King includes the reaction (*i.e.*, oxazolidinedione ring-cleaving) of the compound of formula (III), a  $\Delta^{2,3}$ -*vinyl*substituted compound, with ethylenediamine to produce a compound of formula (IV). The fourth step disclosed in King includes reacting the compound of formula (IV) with DBN or DBU to introduce a double bond at the 1,2 position of the compound. However, King does NOT DISCLOSE the cleaving of an oxazolidinedione ring in a 2-(substituted)-3-*hydroxy*oxazolidinedione of formula (IV), as claimed in the present application.

One embodiment of Applicants' claimed invention is directed to processes for obtaining 17- $\beta$ -(substituted)-3-oxo- $\Delta^{1,2}$ -4-azasteroids of formula (I) which include: (a) cleaving the oxazolidinedione ring in a 2-substituted-3-hydroxyoxalozadinedione of formula (IV), and (b) removing the R<sup>5</sup> substituent present in the compound together with a hydrogen from position 1 of the steroidal nucleus to produce the 17- $\beta$ -substituted azasteroid of formula (I).

Despite the Examiner's assertions to the contrary, King simply does not teach the cleavage of an oxazolidinedione ring of a 3-*hydroxy*-substituted oxazolidinedione. The compounds of King which are subjected to a **de**-oxalylolation (*i.e.*, oxazolidinedione ring cleaving) reaction are  $\Delta^{2,3}$ -*vinyl*-substituted. This reaction, as disclosed by King, is clearly shown in the reaction schematic set forth at the tops of columns 5 and 6 of King wherein the compound of (VI), which is  $\Delta^{2,3}$ -vinyl substituted, is reacted with ethylenediamine and methylenechloride to produce the compounds of formulas (VIII) and (IX). The compound of (VII), shown in King at column 3, is not disclosed as being subjected to a ring cleaving reaction. The compounds of formula (VII) disclosed in King appear to be potential by-products to be avoided. As set forth in King, intermediates in the process disclosed are water-sensitive and "water should be vigorously excluded from the reaction." (*See*, King, column 5, lines 50-51). Given that the reaction scheme disclosed in King at columns 3-6 clearly indicates that water is necessary to arrive at the

compounds of (VII), and King specifically teaches that water is to be “vigorously excluded from the reaction”, it cannot reasonably be concluded that King discloses either expressly, or inherently, that the oxazolidinedione ring-cleaving reaction taught therein is applicable to the 3-*hydroxy*-substituted compounds of formula (VII).

Accordingly, for at least this reason, Applicants respectfully submit that King fails to anticipate the processes embodied in claims 1-5 of the present application.

With respect to the compounds of claims 6 and 7 of the present application, Applicants respectfully submit that King fails to disclose compounds according to the claimed formula (IV) wherein R<sup>5</sup> represents trichloromethylsulfonyl. King does not disclose any trichloromethylsulfonyl substitutes. King discloses only a bromine substitute at the R<sup>5</sup> position of the compounds disclosed therein. Applicant's claimed compounds, as amended herein, are directed to 3-hydroxy-substituted oxazolidinedione compounds substituted at R<sup>5</sup> with trichloromethylsulfonyl. Accordingly, contrary to the Examiner's assertions, King fails to anticipate claims 6 and 7.

With respect to the processes of claims 8-15 of the present application, Applicants further submit that King fails to anticipate these claims. Claims 8 and 9 have been amended herein to specify that the reagent capable of adding hypobromous acid to the compound comprises a component selected from N-bromosuccinimide and 1, 3-dibromo-5,5-dimethylhydantoin. King fails to teach, either expressly or inherently, the use of either reagent for adding hypobromous acid to the double bond at position 2,3 of compound formula (III). The only brominating agent which appears to be disclosed in King is elemental, diatomic bromine (*i.e.*, Br<sub>2</sub>). Thus, Applicants respectfully submit that King fails to anticipate claims 8-13 for at least this reason.

With respect to claims 14 and 15, Applicants respectfully note that the processes embodied in claims 14 and 15 include the cleaving of the oxazolidinedione ring present in the compound of formula (IV) to produce a compound of formula (V). As discussed above, it is respectfully submitted that the claimed process wherein a 3-hydroxy substituted oxazolidinedione ring is cleaved is not taught by King, which is directed to the ring cleavage of a compound having a  $\Delta^{2,3}$ -*vinyl*-substituted structure.

Accordingly, Applicants respectfully submit that King fails to anticipate any of claims 1-15. Reconsideration and withdrawal of the Examiner's rejection under 35 U.S.C. §102(b) based upon King is therefore respectfully requested.

In view of the Remarks set forth above, Applicants respectfully submit that claims 1-5 and 14-15 patentably distinguish over the prior art of record and known to Applicants. Furthermore, in view of the amendments to claims 6-9 and the Remarks set forth above, Applicants respectfully submit that claims 6-13 patentably distinguish over the prior art of record and known to Applicants, as well. Accordingly, withdrawal of the rejection and a Notice of Allowance are respectfully requested.

Respectfully submitted,

Jose Maria Gorgojo Labato, *et al.*

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By:

  
AARON R. ETTELMAN

Registration No. 42,516

**AKIN GUMP STRAUSS HAUER & FELD LLP**

One Commerce Square

2005 Market Street, Suite 2200

Philadelphia, PA 19103-7013

Telephone: 215-965-1200

**Direct Dial: 215-965-1240**

Facsimile: 215-965-1210

E-Mail: aettelman@akingump.com

WWS/ARE/rc